Filed October 6, 2006

Mail Stop Interference P.O. Box 1450 Alexandria, VA 22313-1450 Tel: 571-272-4683 Fax: 571-273-0042

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Stryker Corporation,
Junior Party
(Patent 5,266,683,
Inventors: Hermann Oppermann, Engin Ozkaynak, Thangavel Kuberasampath,
David C. Rueger, Roy H.L. Pang),

v.

Genetics Institute, LLC, Senior Party (Application 08/319,831, Inventors: Rodney M. Hewick, Jack H. Wang, John M. Wozney, Anthony J. Celeste).

> Patent Interference 105,508 (RES) (Technology Center 1600)

DECLARATION - Bd.R. 203(b)1

Part A. Declaration of interference

An interference is declared (35 U.S.C. § 135(a)) between the above-identified parties. Details of the application(s), patent (if any), reissue application (if any), count and claims designated as corresponding or as not corresponding to the count appear in Parts E and F of this DECLARATION.

 $^{^1}$ "Bd.R. x" may be used as shorthand for "37 C.F.R. \S 41.x". 69 Fed. Reg. 49960, 49961 (12 Aug. 2004).

Part B. Judge managing the interference

Administrative Patent Judge Richard E. Schafer has been designated to manage the interference, 37 CFR § 41.104(a).

Part C. Standing order

A Trial Section STANDING ORDER [SO] (Paper 2) accompanies this DECLARATION. The STANDING ORDER applies to this interference.

Part D. Initial conference call

A telephone conference call to discuss the interference is set for 2:00 p.m. on December 1, 2006 (the Board will initiate the call).

No later than **two business days** prior to the conference call, each party shall file and serve (SO ¶¶ 10.1 & 105) a list of the motions (37 CFR § 41.120 & 204; SO ¶¶ 104.2.1, 120 & 204) the narty intends to file.

The time periods for taking action during the motion phase are set in an order accompanying this declaration.

Part E. Identification and order of the parties

Junior Party

Patent:

5,266,683 based on Application 07/841,646 filed

February 21, 1992

Named Inventors:

Hermann Oppermann

Engin Ozkaynak Thangavel Kuberasampath

David C. Rueger Roy H.L. Pang

Title:

Osteogenic Proteins

Assignee:

Stryker Corporation

Senior Party

Application: 08/319,831 filed October 6, 1994

Named inventors: Rodney M. Hewick

Jack H. Wang John M. Wozney

Anthony J. Celeste

Involved Application: 08/319,831 filed October 6, 1994

Title: Bone and Cartilage Inductive Proteins

Assignee: Genetics Institute, LLC

The senior party is assigned exhibit numbers 1001-1999. The junior party is assigned exhibit numbers 2001-2999. 37 CFR § 41.154(c)(1); SO ¶ 154.2.1. The senior party is responsible for initiating settlement discussions. SO ¶ 126.1.

Part F. Count and claims of the parties

Count 1

1. A purified BMP-8 protein or an isolated OP-2 protein comprising the sequence described by residues 1 to 402 of Seq. ID No. 28 of Patent 5,266,683 which protein induces new bone formation in mammals.

The claims of the parties are:

Stryker (Oppermann): Claims 1-58

Genetics (Hewick): Claims 1, 26-29

The claims of the parties that correspond to Count 1 are:

Stryker (Oppermann): Claims 21-26, 27/21, 28, 29, 39, 45-54, 58

Genetics (Hewick): Claims 1, 26-29

The claims of the parties that do not correspond to Count 1, and therefore are not involved in the interference, are:

Stryker (Oppermann): Claims 1-20, 27/6, 27/15, 27/18, 30-38, 40-44, 55-57

Genetics (Hewick): None

The parties are accorded the following benefit for Count 1:

Stryker (Oppermann): None

Genetics (Hewick): Application 07/800,364 November 26, 1991

Part G. Heading to be used on papers

The following heading must be used on all papers filed in this interference, see SO¶ 106.1.1:

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Part H. Order form for requesting file copies

When requesting copies of files, use of SO Form 4 will greatly expedite processing of the request. Please attach a copy of Parts E and F of this DECLARATION with a hand-drawn circle around the patents and applications for which a copy of a file wrapper is requested.

/Richard E. Schafer/ Administrative Patent Judge Enc:

Copy of STANDING ORDER Copy of Patent 5,266,683 Copy of claims of Application 08/319,831

cc (via overnight delivery):

Attorney for Genetics:

Finnegan, Henderson, Farabow, Garrett & Dunner LLP 901 New York Avenue, NW Washington, DC 20001-4413

Attorney for Stryker:

Kirkpatrick & Lockhart Nicholson Graham LLP State Street Financial Center One Lincoln Street Boston, MA 02111-2950 USSN 08/319,831 Page 3

Page 30, line 3, after "NTA" insert --(SEQ ID NO:41)--.

Page 34, line 4, after "TAT" insert --(SEQ ID NO:42)--.

Page 34, line 11, after "GCC" insert --(SEQ ID NO:43)--.

Page 34, line 23, after "with" and before "ATCC" insert -- American Type Culture Collection,

12301 Parklawn Drive, Rockville, Maryland, U.S.A .--

Page 35, line 12, after "CGA" insert --(SEQ ID NO:44)--.

Page 35, Line 27, after "hH38." and before "DNA", insert --Clone hH38 was deposited with the American Type Culture Collection (ATCC), 12301 Parklawn Drive, Rockville, Maryland,

U.S.A., under the accession number 69778 on March 30, 1995 .--

Page 41-53, delete the Sequence Listing and replace it with the enclosed Sequence Listing pages 41-62.

In the Claims:

- (twice amended) A purified BMP-8 protein <u>characterized by:</u> [comprising at least one of]
 - (a) the following sequences:
 - i[a]) Arg-His-Glu-Leu-Tyr-Val-Ser-Phe-Gln-Asp-Leu-Gly-Trp-Leu-Asp-Trp-Val-Ile-Ala-Pro-Gln-Gly-Tyr (SEQ ID NO:1);
 - ii[b]) Leu-Ser-Ala-Thr-Ser-Val-Leu-Tyr-Tyr-Asp-Ser-Ser-Asn-Asn-Val-Ile-Leu-Arg (SEQ ID NO: 2); and
 - iii[c]) Ala-Cys-Cys-Ala-Pro-Thr-Lys (SEQ ID NO: 3);

- [d) Thr-Asn-Glu-Leu-Pro-Pro-Pro-Asn-Lys-Leu-Pro-Gly-Ile-Phe-Asp-Asp-Val-His-Gly-Ser-His-Gly-Arg (SEQ ID NO: 4); and
- e) amino acid #4 (Ala) to #142 (His) of SEQ ID NO:14.]
- a molecular weight of 28,000 38,000 daltons as determined by sodium dodecyl sulfate polyacrylamide gel electrophoresis; and
- (c) a molecular weight of 14,000 20,000 daltons under reducing conditions as determined by sodium dodecyl sulfate polyacrylamide gel electrophoresis said protein being a disulfide linked dimer wherein each of the subunits contains the sequences set forth in part (a) and said protein having the ability to induce the formation of cartilage and/or bone.

Delete claims 2-5, 10-12 and 30.

26. (amended) A pharmaceutical formulation for bone and/or cartilage formation comprising an effective amount of a BMP-8 protein of claim 1 in a pharmaceutically acceptable vehicle.

29. (amended) A pharmaceutical composition for wound healing and tissue repair said composition comprising an effective amount of a BMP-8 protein of claim 1 in a pharmaceutically acceptable vehicle.